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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,809

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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,809	Applicant(s) BERNSTEIN, JOEL E.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2007, has been entered.

Claims 1-17 are pending in the application, with claims 1-8 having been withdrawn as drawn to a non-elected invention. Accordingly, claims 9-17 are being examined on the merits herein.

Applicants' arguments regarding the rejections of the claims have been fully considered but have not been found persuasive. The claims are being rejected as follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1617

Claims 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the specification as originally filed does not provide support for a composition having a non-narcotic analgesic in "unit doses of from about 25 mg to about 1 mg," as recited in claim 13, or a composition having a tricyclic antidepressant "in unit dosages containing 10 mg or less," as in claim 16. Instead, the specification teaches that the non-narcotic analgesic may be provided in amounts of from 0.5 grams to 2.6 grams daily (see paragraph 00010, in particular), but does not teach a composition having the smaller range of from 25 mg to 1 gm of non-narcotic analgesic, as recited in claim 13. The specification also teaches that suitable daily dosages of the tricyclic antidepressant may be in the range of about 2.5 mg to about 25 mg daily (see paragraph 00011, in particular), but does not teach providing the tricyclic in range of 10 mg or less, as recited in claim 16. Accordingly, as claims 13 and 16 are not fully supported by the specification as originally filed, these claims are deemed to add impermissible new matter, and are rejected under 35 U.S.C. 112, first paragraph. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank S. Caruso, published November 12, 1998.

Caruso teaches treating neuropathic pain with a composition having an antidepressant (see abstract, in particular.) Caruso teaches that the antidepressant can be a tricyclic antidepressant such as imipramine hydrochloride, doxepin hydrochloride, among others (see page 4, lines 1-19, in particular.) Caruso teaches that an oral method of administration can be employed, and the composition may be provided as tablets or hard capsules, which are pharmaceutically acceptable vehicles (see page 6, lines 5-12, in particular.) Caruso furthermore teaches that the composition can have a non-narcotic analgesic such as acetaminophen or naproxen (see page 7, lines 10-24, in particular.) Caruso also teaches that the composition can be formulated to provide a desired dosage level of the components per day, and teaches formulating with pharmaceutically acceptable ingredients and excipients (carriers) (see page 5, lines 20-25 and page 6, lines 10-25, in particular.)

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 9-15, Caruso teaches exemplary tablet dosage forms having antidepressant drugs and an additional active component that is a non-narcotic analgesic (see page 10, lines 5-37, in particular.) Regarding claims 11-12 and 14-15, Caruso teaches that the tablet form can comprise compositions with 25 mg of imipramine hydrochloride and 325 mg of aspirin or acetaminophen (see examples 36 and 37, in particular.) Thus, Caruso teaches the composition having the claimed tricyclic antidepressant compounds and non-narcotic analgesics, and also teaches the claimed pharmaceutically acceptable vehicle.

Regarding claims 9-10, Caruso's teaching of 25 mg of imipramine hydrochloride is considered to meet the limitation of being a "low dose" of tricyclic antidepressant compound as claimed, because it falls within the range of "about 25 mg/day or less," in accordance with the definition of the "low dose" as set forth by Applicants in the first full paragraph on page 3 of the specification. Caruso's teaching thus also meets the limitation of being from "about" 2.5 mg to "about" 25 mg daily as recited in claim 10.

Regarding claims 9, 13 and 17, Caruso's teaching of 325 mg of acetaminophen is considered to meet the limitation of being a "standard dose" of non-narcotic analgesic compound as claimed, because it falls within the range of "about 0.5 grams to about 2.6 grams," in accordance with the Applicants' guidance of a suitable "standard dose," which is set forth in the second full paragraph on page 3 of Applicants' specification. In particular, 325 mg of acetaminophen is considered to be within the range of "about" 0.5 grams to "about" 2.6 grams, as set forth by Applicants, as well as the dose of from about 25 mg to about 1 gm as in claim 13, and about 50 mg to about 2.6 grams, as recited in claim 17.

Accordingly, the tablet dosage forms taught by Caruso anticipate the compositions of claims 9-15 and 17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11, 13-14 and 16-17 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "The Role of Antidepressants in the Treatment of Chronic Pain" by Kakuyama et al, 2000, Pain Reviews, Vol. 7, pages 119-128.

Kakuyama et al. teaches treatment of chronic pain with antidepressants, noting that the efficacy of treatment of chronic pain with antidepressant has been assessed in many randomized controlled studies, and that tricyclic antidepressants are the first line treatment for chronic pain such as postherpetic neuralgia and painful diabetic neuropathy, and are also effective for migraine and chronic tension-type headache (see abstract, in particular.)

Kakuyama et al. teaches that patients suffering from fibromyalgia achieved significant improvement in their condition after receiving naproxen (an NSAID) in an amount of 1000 mg/day and amitriptyline in an amount of 25 mg each night, for a duration of six weeks (see page 125, right hand column fourth full paragraph, in particular.) Thus, Kakuyama et al. teaches the desirability of providing a non-narcotic analgesic in an amount that meets the limitation of being a "standard dose," as defined by Applicants on page 3 of the specification, as well as recited in instant claim 17, and providing a tricyclic antidepressant in an amount that meets the limitation of being a "low dose," as defined by Applicants in the paragraph bridging pages 3-4 of the specification, as well as recited in instant claim 10.

Kakuyama et al. does not specifically teach that the "standard dose" of naproxen and "low dose" of amitriptyline are provided together in the same composition. However, as Kakuyama et al. teaches that the administration of the combination of

Art Unit: 1617

compounds is suitable for the treatment of fibromyalgia, it is considered that one of ordinary skill in the art at the time of the invention would have found it obvious to combine the compounds into a single compositions, with the expectation of providing a composition suitable for fibromyalgia treatment. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, claims 9, 10 and 17 are obvious over the teachings of Kakuyama et al.

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 11 and 14, Kakuyama et al. teaches providing amitriptyline and naproxen (and NSAID), and thus teaches providing the tricyclic antidepressant and NSAID, as recited in the claims.

Regarding claims 13 and 16, it is noted that Kakuyama et al. teaches a daily dosage of amitriptyline and naproxen that is efficacious in the treatment of fibromyalgia,

Art Unit: 1617

as discussed above. Accordingly, it is considered that one of ordinary skill in the art at the time of the invention would have found it obvious to vary and/or optimize the drugs provided in a unit dosage, such as to provide twice a day or three times a day dosage, as well as to optimize treatment efficacy, with the expectation of providing a suitable treatment for fibromyalgia. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "The Role of Antidepressants in the Treatment of Chronic Pain" by Kakuyama et al, 2000, Pain Reviews, Vol. 7, pages 119-128, as applied to claims 9-11, 13-14 and 16-17 above, and further in view of WO 98/50044 to Caruso et al, published November 12, 1998.

Kakuyama et al. is applied as discussed above, and renders obvious a composition comprising a "low dose" of amitriptyline and a "standard dose" of naproxen for the treatment of fibromyalgia.

Kakuyama et al. does not specifically teach providing the amitriptyline in the form of one of the acid addition salts as recited in claim 12. Kakuyama et al. also does not

specifically teach the pharmaceutically acceptable vehicles such as tablets, capsules, caplets, etc, as recited in claim 15.

Caruso et al. teaches that it is known to provide the anti-depressant amitriptyline as a pain-relieving agent in the hydrochloride salt form (see page 4, in particular.) Caruso et al. also teaches that it is known to deliver drugs such as antidepressants in pharmaceutically acceptable forms such as tablets or hard capsules (see page 6, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the hydrochloride salt form of the amitriptyline as taught by Caruso et al., as well to provide the amitriptyline and naproxen combination in the form of a tablet or hard capsule, in the composition and method of Kakuyama et al, because Kakuyama et al. teaches that the combination can be suitably administered for the treatment of fibromyalgia, whereas Caruso et al. teaches that the hydrochloride salt form and tablet or hard capsules are suitable forms for the administration of the pharmaceutical drugs. Accordingly, one of ordinary skill in the art would have been motivated to provide the hydrochloride salt form and tablet or capsule dosage form with the expectation of achieving a composition suitable for pharmaceutical administration for the treatment of fibromyalgia. Accordingly, claims 12 and 15 are obvious over the teachings of Kakuyama et al. in view of Caruso et al.

Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over WO 98/50044 to Caruso et al, published November 12, 1998.

Caruso et al. is applied as discussed above, and teaches compositions for alleviating pain comprising an antidepressant (see abstract, in particular.) Caruso et al. also teaches that the pain relief composition can also contain other analgesics such as acetaminophen and aspirin (see page 7, in particular), and further exemplifies a unit dosage form containing 25 mg of imipramine hydrochloride (tricyclic antidepressant), and 325 mg of either acetaminophen or aspirin (analgesic) (see Examples 36-37, in particular.)

Caruso et al. does not specifically teach a dosage form having 10 mg or less of tricyclic antidepressant, as recited in claim 16.

However, Caruso et al. teaches that the desired dosage of the tricyclic can be determined through routine experimental testing, and can be optimized relative to the dosage level of an NMDA receptor antagonist being concomitantly administered (see page 5, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of tricyclic antidepressant provided in the composition, according to the guidance provided by Caruso et al, to provide a composition having desired properties, such as desired synergistic operation with the NMDA receptor antagonist. It is noted

that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,579,846 to Crawford et al, issued April 1, 1986, in view of U.S. Patent No. 4,434,164 to Joseph G. Lombardino, issued February 28, 1984.

Crawford et al. teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant) (see abstract and column 3, lines 45-58, in particular.) Crawford et al. teaches that the piroxicam can be provide in a range of 0.1 to 1 mg/kg/day, whereas the second ingredient, such as doxepin, can be provided separately in an amount that is generally lower than the dosages typically specified in the prior art (see column 3, lines 45-55, in particular.) Crawford et al. also teaches that in a combined formulation, the proportion of each drug is the ratio of the total daily dosage of each drug when dosed alone (see column 3, lines 55-68, in particular.) That is, Crawford et al. teaches that the combined formulation could comprise the (i) 0.1 mg/kg/day dose of piroxicam with (ii) the lower dose of doxepin that is taught by Crawford et al. as being provided if the drugs are administered alone (i.e. not in combination, separately.) Crawford et al. also exemplifies a treatment composition comprising 20 mg of piroxicam and 20 mg doxepin with lactose

Art Unit: 1617

and hydroxypropyl methylcellulose (carriers), and teaches that a dosage of the piroxicam can be from 5-50 mg/day (see Example 9 and column 4, lines 1-10, in particular.)

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Crawford et al. does not specifically teach that the compositions as exemplified comprise a "standard dose" of a non-narcotic analgesic and a low dose of a tricyclic antidepressant, as recited in claim 9.

Lombardino teaches novel salts of piroxicam that provide anti-inflammatory activity (see column 1 line 1 through column 2 line 60, in particular.) Lombardino teaches that a suitable dose of the piroxicam salt can be from 5 mg up to 1000 mg per day (see column 3, lines 18-25, in particular.)

Accordingly, Crawford et al.'s dosage of 5 to 50 mg/day (see column 4, lines 1-10, in particular), falls within the dosage range as taught by Lombardino et al. to be useful for anti-inflammatory action, and thus is considered to be a "standard dose" of piroxicam. Accordingly, it is considered that one of ordinary skill in the art at the time

the invention was made would have found it obvious to provide the "standard" normal dose of piroxicam as taught by Crawford et al. and Lombardino, with a lower dose of doxepin, as taught by Crawford et al, with the expectation of providing a suitable anti-inflammatory composition for the treatment of gastric irritation.

Regarding claims 13 and 17, Crawford et al's teaching of 5 to 50 mg/day of piroxicam meets and/or overlaps with the limitation of being from "about 25 mg to about 1 gm," as in claim 13, and "about 50 mg to about 2.6 gm," as in claim 17. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of piroxicam provided in the composition, according to the guidance provided by Crawford et al, to provide a composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 10 and 16, Crawford et al. teaches that the dosage of doxepin can be from 4 to 200 mg/day (see column4, lines 5-10, in particular), and exemplifies a composition with 20 mg, and thus meets the limitation of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of doxepin provided in the composition, according to the guidance provided by Crawford et al, to provide a

composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 11, Crawford et al. teaches providing doxepin, as recited in the claim. Regarding claim 12, Crawford et al. teaches that doxepin is marketed in the form of its hydrochloride salt (see column 3, lines 15-20, in particular), and thus it would be obvious to one of ordinary skill in the art to provide doxepin hydrochloride because Crawford et al. teaches that this is a doxepin form that available on the market. Regarding claim 14, Crawford et al. teaches providing piroxicam, which is a non-steroidal anti-inflammatory. Regarding claim 15, Crawford et al. teaches that the composition can be provided as a tablet or capsule (see column 4, lines 15-20, in particular.)

Response to Arguments

Applicant's arguments filed April 12, 2007 have been fully considered but they are not persuasive.

In particular, Applicants have provided references (Harrison's 14th Edition and The Pharmacological Basis of Therapeutics) showing what is considered to be a

Art Unit: 1617

"standard dose" of non-narcotic analgesic and "low dose" of tricyclic antidepressant.

Harrison's teaches that a typical dosage of naproxen is 250-500 mg PO, every 12 hours (or 500-100 mg/day), and a typical dose of amitriptyline ranges from 25-300mg/day, with the average dose being 150 mg/day (see Table 12-2.) Thus, even according to this reference, the teaching by Kakuyama et al. of 1000 mg/day of naproxen and 25 mg/day of amitriptyline, as discussed above, appears to correspond to a "standard dose" of the naproxen, and a dose of amitriptyline that is on the lower end of the typical dosage range, and thus is a "low dose" of the amitriptyline. The Pharmacological Basis of Therapeutics teaches that a usual dose of amitriptyline is from 100-200 mg/day, with an "extreme dose" ranging from 25-300 mg/day (see Table 19-1, in particular.) Accordingly, this reference also appears to show that 25 mg/day, the dosage level taught by Kakuyama et al, corresponds to a dosage that is considered to be unusually low as compared to the usual amitriptyline dosage, and thus meets the limitation of being a "low dose" as recited in the claims.

Conclusion

No claims are allowed.

The prior art made of record and not being relied upon that is considered pertinent to applicant's disclosure is cited in the accompanying PTO-892 form.

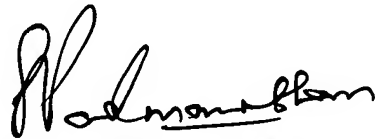
Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC


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SUPERVISORY PATENT EXAMINER